Wound Management and Estimated Cost Associated With Dermal Templates Containing 10% Extracellular Matrix Components and 90% Intact Collagen.

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Introduction/Aim:

Chronic leg ulcerations are a burdensome malady in terms of quality of life, economics, and health resource utilization. An analysis by others of venous leg ulcer (VLU) healing finds that there is upwards of 60% closure in 20 weeks.[1] Direct costs of ulcer care are incurred by the patient and payer through clinic outpatient visits, home visits, dressings, and inpatient stays, while indirect costs resulting often for lost wages are societal in their reach. It is estimated that in the US VLU's can cost upwards of 2.5 billion dollars annually.[2,3] This retrospective case series describes the outcome of three patients, each with a venous leg ulcer. In all three cases, the ulcer closed during the use of a dermal template containing 10% extracellular matrix components and 90% intact collagen.* Health care management costs are estimated based on a model considering clinician time and product cost.

Methods:

Data was extracted from a proprietary wound database (Woundtech, Hollywood, FL) utilizing Woundtech's Product Analysis Data System (PADS) and consisting of information regarding multiple comorbidities, wound etiologies, percent changes in wound size, and wound treatment/management regimes. Patients with a venous leg ulcer in which the data demonstrated records of continuous management were eligible for inclusion. Three patients with positive outcomes and demonstrating continuity of management were selected for analysis.

The primary outcome of interest was percent decrease in wound area from baseline and was analyzed via linear regression and graphical methods.

Health care management costs are estimated based on a model considering Medicare reimbursement codes 99203, 99212, and 99213.

Results:

Graph 1 shows wound progression over time as a function of percent wound closure, where 100 percent signifies a fully closed wound; the data points indicated dressing changes. A positive rate of closure was noted within 2 days from onset of treatment for the three patients and all wounds closed within four weeks. **Table 1** presents individual case outcomes.

Actual management costs were not available. Estimated health care management costs at 4 weeks are shown in Graph 2 and represent the estimated management costs (resource costs) to include dermal template (Endoform: GHX 2014 Average Sale Price for Hospitals4), cost of gauze and tape, and cost of nurse/physician reimbursable time at 2 visits per week based on a model which considers Medicare reimbursement codes for new patients (99203), and existing patients (99212, 99213).

Shown are resource estimates for the use of a 2"x2" and 4"x5" product. Estimated average resource cost at four weeks for a 2"x2" product is $276.52; for the 4"x5" product $504.60.

Conclusions:

This retrospective case series describes the outcome of three patients with chronic venous leg ulcers. The wounds described here closed during the use of a commercially available dermal template containing 10% extracellular matrix components and 90% intact collagen. In the three situations described the wounds moved to complete closure within four weeks. A limitation of this study was the non-availability of actual cost. Average costs for management, estimated for four weeks, are $276.52 when estimated for a 2"x2" dermal template and $504.60 with a 4"x5" dermal template.

Case Study 1

93 year old female with a right lower leg venous ulcer. Patient has no recorded history of comorbidities.

Case 1 (day 0)

Case Study 2

77 year old female with a right ankle venous ulcer. Patient has a history of diabetes with neurological manifestations, edema, obesity, and peripheral autonomic neuropathy in disorders classified elsewhere.

Case 2 (day 0)

Case Study 3

76 year old male with a right lower leg venous ulcer. Patient has a history of diabetes with peripheral circulatory disorders, polyneuropathy in diabetes, and unspecified peripheral vascular disease.

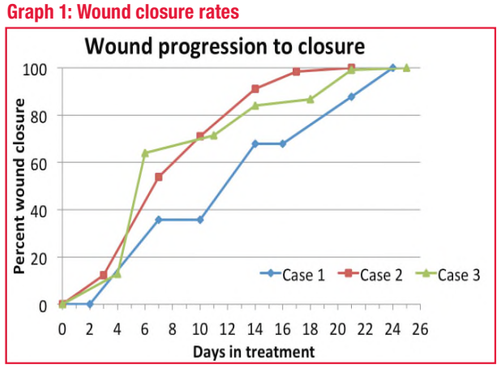
Case 3 (day 0)

Table 1: Individual case outcomes

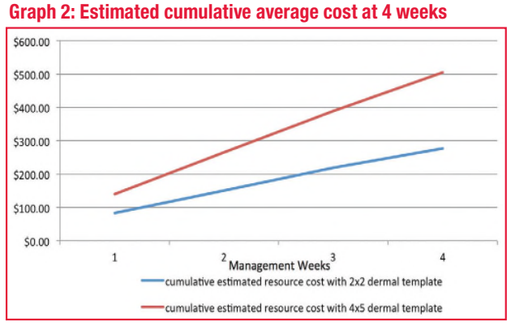
	# of dressing changes	Days to wound closure	Daily percent closure*
Case 1	8	24	4.0% (R^2=0.83)
Case 2	7	21	5.2% (R^2=0.92)
Case 3	8	25	4.3% (R^2=0.98)

* Determined via linear regression analysis

Graph 1: Wound closure rates



Graph 2: Estimated cumulative average cost at 4 weeks



[1] Steed DL, Hill DP, Woodske ME, Payne WG, Robson MC. Wound-healing trajectories as outcome measures of venous stasis ulcer treatment. Int Wound J 2006;3:40-7.
[2] Bohn G, Gass K. Leg Ulcer Treatment Outcomes with New Ovine Collagen Extracellular Matrix Dressing: Retrospective Case Series. Adv Skin Wound Care, 27(10):448-454, October 2014
[3] Collins L, Seraj S. Diagnosis and treatment of venous ulcers. Am Fam Physician 2010;81:989-96
[4] Source Hollister Incorporated

* Endoform™ dermal template, Hollister Incorporated

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